

Re: Zosyn®
Docket No. 94E-0071OFFICE OF THE ASSISTANT
COMMISSIONER FOR PATENTS

MAY - 1 1995

RECEIVED

APR 18 1995

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,562,073, filed by Taiho Pharmaceutical Company, Ltd., under 35 U.S.C. § 156 et seq. The Food and Drug Administration (FDA) is correcting the notice of its determination of the regulatory review period for purposes of patent extension for Zosyn® (tazobactam sodium) that appeared in the Federal Register of August 30, 1994 (page 44,738). The notice stated:

FDA has determined that the applicable regulatory review period for Zosyn® is 1,819 days. Of this time, 1,038 days occurred during the testing phase of the regulatory review period, while 781 days occurred during the approval phase.

1. The date an exemption under 505(i) of the Federal Food, Drug, and Cosmetic Act became effective: October 31, 1988. The applicant claims July 10, 1988, as the date the investigational new drug application (IND) for Zosyn® (IND 31,705) became effective. However, IND 31,705 was received on June 14, 1988, and it was placed on clinical hold on July 1, 1988. It was removed from clinical hold on October 31, 1988, making the IND effective date October 31, 1988.

It should have stated:

FDA has determined that the applicable regulatory review period for Zosyn® is 1,906 days. Of this time, 1,125 days occurred during the testing phase of the regulatory review period, while 781 days occurred during the approval phase.

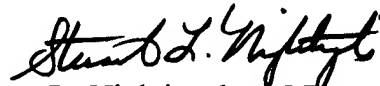
1. The date an exemption under 505(i) of the Federal Food, Drug, and Cosmetic Act became effective: August 5, 1988. The applicant claims July 10, 1988, as the date the investigational new drug application (IND) for Zosyn®

Zosyn® - Page 2

(IND 31,705) became effective. However, IND 31,705 was received on June 14, 1988, and it was placed on clinical hold on July 1, 1988. It was removed from clinical hold on August 5, 1988, making the IND effective date August 5, 1988.

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Stuart L. Nightingale".

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Richard J. Berman
Nikaido, Marmelstein, Murray & Oram
655 Fifteenth Street, N.W., Suite 330
Washington, D.C. 20005-5701